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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/007,158	12/05/2001	Jane Brandman	A0000483-01-CA	4222

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EXAMINER	
HUI, SAN MING R	
ART UNIT	PAPER NUMBER
1617	6

DATE MAILED: 10/01/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/007,158	Applicant(s) BRANDMAN ET AL.	
	Examiner San-ming Hui	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 August 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) *1-5* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *3* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Applicant's election of the invention of Group II, claims 6-12 in Paper No. 5, received August 29, 2002, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-5 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 5.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The expression "preventing ... acne in a patient in need of treatment" in claim 6 renders the claim indefinite. It is unclear what patient population is encompassed by the claims. How can a patient who needs the treatment (i.e., already have the disease) be prevented from having the disease? Moreover, even though the definition of prevent acne is disclosed in the specification, it is still unclear the degree of slowing or averting the occurrence of acnes is encompassed by the claims. Is it partial prevention or total

prevention? Examiner would favorably consider expressions such as "reduce the occurrence of..." over the phrase "preventing ... acne".

Claim 11 contains the trademark/trade name "Estrostep". Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe a fixed amount combination of norethindrone acetate and ethinyl estradiol and, accordingly, the identification/description is indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 6 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Redmond 1(Obstetrics & Gynecology, 1997; 89(4): 615-622 from the IDS received May 20, 2002).

Redmond 1 teaches a triphasic combination of norgestimate and ethinyl estradiol is effective in treating acne vulgaris (See particularly the abstract).

Claims 6 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Redmond 2 (Contraception, 1998; 58: 29S-33S from the IDS received May 20, 2002).

Redmond 2 teaches a triphasic combination of norgestimate and ethinyl estradiol (TriCyclen® with gradually increased norgestimate dosage of 0.18, 0.215, 0.25 μg and fixed ethinyl estradiol daosage of 35μg) is effective in treating acne vulgaris (See particularly the abstract).

Claims 6-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Thorneycroft et al. (Contraception, 1999; 60(5): 255-262).

Thorneycroft et al. teaches that Alesse® (containing 100μg of levonorgestrel and 20μg of ethinyl estradiol) and Loestrin® Fe 1/20 (containing 1mg of norethindrone acetate and 20Mg of ethinyl estradiol) are effective in reducing acne (See particularly the abstract, also page 257, col. 2 – page 259, col. 2; also Figure 2 and Tables 3 and 4).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 8-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Redmond 2 and Thorneycroft et al. (Contraception, 1999; 60(5): 255-262) over Schoonen (The Journal of Steroid Biochemistry & Molecular Biology, 2000;74(2):213-222) and Boissonneault (US Patent 5,010,070 from the IDS received May 20, 2002).

Redmond 2 teaches an oral contraceptive, triphasic combination of norgestimate and ethinyl estradiol (TriCyclen® with gradually increased norgestimate dosage of 0.18, 0.215, 0.25 μg and fixed ethinyl estradiol daosage of 35μg), is effective in treating acne vulgaris (See particularly the abstract). Redmond 2 also teaches the rationale of selecting TriCylcen in the treatment of acne because ethinyl estradiol is known to increase serum levels of sex hormone binding globulin and thereby lower the testosterone level (See page 30S, col. 2, fourth paragraph). Moreover, Redmond 2 teaches that the progestins, norgestimate, has low androgenicity and does not counteract the estrogen-mediated rise in sex hormone binding globulin which results in the decrease of testosterone levels (See page 30S, col. 2, fourth paragraph).

Thorneycroft et al. teaches two oral contraceptives, Alesse® (containing 100μg of levonorgestrel and 20μg of ethinyl estradiol) and Loestrin® Fe 1/20 (containing 1mg of

norethindrone acetate and 20μg of ethinyl estradiol), are effective in reducing acne (See particularly the abstract, also page 257, col. 2 – page 259, col. 2; also Figure 2 and Tables 3 and 4). Thorneycroft et al. also teaches that both levonorgestrel and norethindrone acetate can reduce the androgen levels (See the abstract). Thorneycroft et al. also teaches that both Alesse® and Loestrin® Fe 1/20 are significantly reduce the totals testosteron and increase the SHBG level (See page 258, Figure 1).

The references do not expressly teach the specific herein claimed dosage regimen of Estrostep or an effective amount of 1mg norethindrone acetate and a gradually increasing dose of ethinyl estradiol: 20μg for 5days, 30μg for 7 days and 35μg for 9 days.

Schoonen teaches norethindrone (also known as Norethisterone) has a very weak androgenicity and estrogenicity (See particularly the abstract).

Boissonneault teaches the specific herein claimed regimen of norethindrone acetate and ethinyl estradiol is useful as oral contraceptive (See col. 3, Table 1).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the herein claimed regimen of administering norethindroe and ethinyl estradiol to treat acne vulgaris.

One of ordinary skill in the art would have been motivated to employ the herein claimed regimen of administering norethindrone acetate and ethinyl estradiol to treat acne vulgaris. Firstly, based on the cited prior art, it is known that different oral contraceptives containing different progestins and ethinyl estradiol, such as TriCylen®, Alesse®, and Loestrin® Fe 1/20, are useful in treating acne vulgaris. Therefore, using

yet another known oral contraceptives, such as Estrostep (taught by Boissonneault), in the treatment of acne vulgaris would be reasonably expect to be effective. Secondly, norethindrone acetate is known to have weak androgenicity and known to reduce the testosterone levels. Therefore, based on Redmond 2, substituting a progestin that has low androgenicity and would reduce testosterone level, such as norethindrone acetate, for norgestimate in the oral contraceptives would be reasonably expected to be effective in treating acne. Thirdly, the optimization of result effect parameters (e.g., dosing regimens) is obvious as being within the skill of the artisan.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (703) 305-1002. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (703) 305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

San-ming Hui
September 30, 2002

SREENI PADMANABHAN
PRIMARY EXAMINER

9/30/02